K002083

FEB 1 2 2001

TAB 5 – Summary of Safety and Effectiveness

Device Name: Lorenz Resorbable Distractor System

Classification Name and Reference: Plate, Fixation, Bone (21 CFR 888.3030); and Screw, Fixation, Bone (21 CFR 888.3040)

Product Code: 76 JEY

Device Classification: Class II

The Alveolar Ridge Resorbable Distractor and the Mid-Face (LeFort III) Resorbable Distractor are implantable distractors similar to the Lorenz Maxilla (LeFort) Distraction System (K982604) having a metallic drive screw mechanism and connection plates. However, these devices will be composed of Lactosorb® end plates and fixation screws, and titanium alloy drive screws. After consolidation, only the metal transport components need to be removed.

The Alveolar Ridge Distractor is an implantable device used to increase the height of the maxilla or mandible to replenish lost bone of the alveolar process. The device is composed of two resorbable plates and a titanium alloy drive screw. The device has two different sizes, small plates for single tooth use and large plates for multiple tooth deficiencies. Several lengths of drive screw can be selected to achieve up to 25 mm of distraction.

The device is placed and activated intra-orally. After a small rectangular resection of alveolar ridge bone is detached, the stationary plate of the device is affixed to the remaining non-resected bone of the maxilla or mandible using 1.5 mm resorbable screws. The movable plate is then affixed to the resected segment also using 1.5 mm resorbable screws and distraction is achieved by turning the drive screw causing the plates to separate. At the completion of the distraction and consolidation, the drive shaft is detached and removed. The plates and screws remain internal and are resorbed.

The Mid-Face (LeFort III) Resorbable Distractor is an implantable device used for the reconstruction of the mid-face. The device has both a left and right component that are normally to be used together in a single procedure. Each device is composed of two resorbable plates and a titanium drive screw. Two lengths of drive screw can be selected to achieve up to 40 mm of linear distraction.

Each device is placed internally with the drive mechanism protruding through the skin, posteriorly. The mid-face is resected at the LeFort level and the anterior stationary plate is placed around the orbit using 2.0 mm resorbable screws. The movable plate is attached posteriorly to the temporal bone using 2.0 mm resorbable screws. Distraction is achieved by activating the drive screw causing the plates to

separate. Upon completion of the distraction and consolidation, the drive shaft is detached from the plates and removed while the plates and screws remain internal and are resorbed.

Intended Use: The Lorenz Resorbable Distraction System includes devices intended for use in bone stabilization and elongation (lengthening) when correction of oral (alveolar ridge), cranial, and maxillofacial deficiencies or post-traumatic defects require gradual bone distraction. The mid-face distractor is intended primarily for LeFort III osteotomies.

Materials Bone Plates: Lactosorb® (resorbable copolymer) – a polyester derivative of lactic and glycolic acids
Bone Screws: Lactosorb®
Drive Screw: Titanium 6Al-4V alloy (ASTM F-136)

Lactosorb® is made of 82% L-Lactide/18% Glycolide copolymer that degrades by hydrolysis into L-Lactic and glycolic acids. These hydrolytic products are then further degraded into carbon dioxide and water via the cellular Krebs cycle. Lactosorb® has been previously cleared by 510(k) notifications for use in bone plates (K992355, K992158, K971870, K960988, K955729) and bone screws (K981666, K960988) for cranial and maxillofacial use.

Potential Risks

POSSIBLE ADVERSE EFFECTS AND COMPLICATIONS

1. Poor bone formation, osteoporosis, osteolysis, osteomyelitis, inhibited revascularization, or infection can cause loosening, migration, bending, cracking or fracture of the device.
2. Nonunion or delayed union may lead to breakage of the implant.
3. Bending, loosening, stripping the threads or fracture of the implant.
4. While rare, implantation of foreign materials can result in an inflammatory response or allergic reaction.
5. If metal parts of the device remain implanted, decrease in bone density due to stress shielding.
6. Pain, discomfort, abnormal sensation, or palpability due to the presence of the device.
7. Nerve damage due to surgical trauma.
8. Necrosis of bone.
9. Biomechanical complications after distraction due to positioning of the device.
10. Tension of the soft tissue depending on the speed of distraction and quality of the soft tissues and therefore irritation and / or atrophy.
11. Inadequate healing.
12. Other conditions brought on by the surgical procedure including skin irritation and infection.

Apart from these adverse effects there are always possible complications of any surgical procedure such as, but not limited to, infection, nerve damage, and pain which may not be related to the implant.

Substantial Equivalence

Distraction Systems
Lorenz Maxilla (LeFort) Distraction System (K982604)
Lorenz Distraction System (K992952)
Howmedica Leibinger Guerrero-Bell (K972166) & Cohen Distractors (K972154)
KLS Martin Alveolar Ridge Distractor (K983515)
Synthes Mini Lengthening Apparatus (K973018)

Resorbable Fixation Screws and Plates
Lactosorb® Trauma Plating System (K971870)
Lactosorb® Trauma Plating System (K955729)
2.5 MM Lactosorb® Screws (K981666)
Lactosorb® Panels (K974309)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 12 2001

Mr. Steve Herrington
Walter Lorenz Surgical, Incorporated
1520 Tradeport Drive
Jacksonville, Florida 32218

Re: K002083
Trade Name: Lorenz Resorbable Distraction System for Mid-Face & Alveolar Ridge
Regulatory Class: II
Product Code: JEY
Dated: November 9, 2000
Received: November 14, 2000

Dear Mr. Herrington:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does

not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

STATEMENT OF INDICATIONS FOR USE

510(k) Number K002083

Device Name: Lorenz Resorbable Distraction System for Mid-Face & Alveolar Ridge

Indications for Use:

The Lorenz Resorbable Distraction System includes devices intended for use in bone stabilization and elongation (lengthening) when correction of oral (alveolar ridge), cranial, and maxillofacial deficiencies or post-traumatic defects require gradual bone distraction. The mid-face distractor is intended primarily for LeFort III osteotomies.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter-Use_____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K002083

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